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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/729,631
Filing Date: December 05, 2003
Appellant(s): SHANLEY ET AL.

SHANLEY *et al.*
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 18, 2006 appealing from the Office action mailed May 16, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 6,656,162	SANTINI et al.	12-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 49-51, 53, 56-62, 74-78, and 81-86 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Santini, Jr. et al. (US 6,656,162; cited in Applicants' IDS). The rejection below is as set forth in the Final Rejection mailed on May 16, 2005.

As seen in Figures 1, 2A-2E, 9A, and 9C, Santini, Jr. et al. disclose an expandable medical device comprising (i) a substantially cylindrical expandable medical device formed of a plurality of struts (see Figures 9A and 9C; see column 10, lines 44-67; column 14, line 63 to column 15, line 23), (ii) a plurality of openings (i.e., reservoirs) in the plurality of struts (see Figures 9A and 9C; see column 10, lines 44-67; column 14, line 63 to column 15, line 23), and (iii) a plurality of beneficial agent layers (i.e., an anti-proliferative, or, an anti-inflammatory, or, a protein drug: either in "pure form" or embedded in a biodegradable polymeric matrix) formed in the openings, wherein the plurality of beneficial agent layers (see column 5, lines 30-33) include a first active agent arranged for delivery according to a first release profile (e.g., Figure 2d, agent 540a; see column 4, lines 33-62; column 5, lines 20-37) and a second active agent arranged for delivery according to a second release profile (e.g., Figure 2d, agent 540b; see column 4, lines 33-62; column 5, lines 20-37). A barrier layer (reservoir cap and/or backing plate) is formed within the openings to block or retard delivery of the first and second active agents to the luminal side of the device body (see entire document).

(10) Response to Arguments

A. With regards to arguments (i), (ii), and (iii), the Applicants argue that Santini et al. '162 does not teach an expandable device comprising an expandable body formed of a plurality of struts, and a plurality of openings in the plurality of struts; that Santini is "at least partially non-

enabling"; and "Appellant vigorously disputes that Santini's microchips can be formed as part of a stent based on this disclosure".

Santini et al. '162 clearly disclose "*integrating one or more drug delivery microchips into/onto a stent, such as a vascular stent*" (see column 14, lines 64-66). Figure 9A of Santini et al. '162 is an exemplary embodiment of drug delivery microchips integrated onto a stent. As an alternate embodiment, Santini et al. '162 clearly disclose "*In another embodiment, stents can be designed and fabricated to have drug reservoirs and caps as part of the stent itself, that is, not as a separate microchip device, but rather as part of a monolithic stent device*". It should be noted that this portion of the disclosure teaches "drug reservoirs and caps" as monolithically formed with the stent structure. The disclosure of Santini et al. '162 offers a few examples of stent structures that are well known in the art (see column 11, lines 5-12), which examples includes expandable stent structures comprising a plurality of struts and drug(s)/agent(s) deposited therein (e.g., US 5,670,161; US 5,464,450). The Examiner maintains that the disclosure of Santini et al. '162 is enabling, and will enable one of ordinary skill in the art to reduce to practice the above-mentioned teaching: "*stents can be designed and fabricated to have drug reservoirs and caps as part of the stent itself, that is, not as a separate microchip device, but rather as part of a monolithic stent device.*"

B. With regards to the combination of independent claim 49 and dependent claims 57 and 58, the Appellant argues that Santini et al. '162 "is completely silent about the release profiles of the molecules from their respective reservoirs, and certainly fails to describe release profiles". It should be noted that the language of claim 49 requires blocking or retarding "delivery of the first and second active agents to the luminal side of the device body through the openings". As clearly

shown in the exemplary embodiment of Figure 9c, the reservoir cap is facing the luminal side of the device, and said reservoir cap will "block or retard delivery of the first and second active agents to the luminal side of the device body through the openings". In the embodiment shown in Figure 2D, since there is a barrier layer (reservoir cap 530b) between first active agent layer 540a and second active agent layer 540b, then the release profiles will inherently be different. The release profile is either by passive release, or by active release.

C. With regards to claim 50, the claim recites the following intended purpose: "wherein the first and second active agents are arranged to be delivered to a mural side of the device body". With regards to the direction (e.g., mural or luminal) of drug delivery, Santini et al. clearly teaches the drug delivery reservoirs as disposed into or onto the stent (see column 14, lines 63-66), and the skilled artisan will be left with the choice of deciding the direction of drug delivery, depending on the intended purpose. If the drug delivery reservoirs are disposed into the stent, then the drugs will be exposed (after degradation of the barrier layer) to either the mural or luminal side of the stent.

D. With regards to claim 51, the Appellant argues: "nowhere does Santini disclose to the skilled artisan that a stent has one reservoir including an anti-proliferative and another reservoir including an anti-inflammatory or the direction that these should be delivered from the stent". It is noted that claim 51 broadly claims "wherein the first active agent is an anti-proliferative and the second active agent is an anti-inflammatory", but it is silent as to one reservoir including an anti-proliferative and another reservoir including an anti-inflammatory. Santini et al. '162 teach that the first and second active agents can be the same or different (see column 4, lines 38-41). Examples of the drug/agent (e.g., anti-inflammatory) to be delivered are disclosed in column 9,

lines 34-67. The use of stents carrying anti-proliferative and/or anti-inflammatory agents/drugs is well known in the art (column 2, lines 28-32).

E. With regards to claim 53, the Appellant argues that Santini et al. '162 does not teach "the barrier layer is formed within the openings". Figure 2D clearly shows reservoir cap 530b (i.e., a barrier layer) formed within the openings. Also, reservoir cap 530a (i.e., a barrier layer) may include a portion that is disposed within the openings (column 2, lines 6-8).

F. With regards to claim 56, the Appellant argues that Santini et al. '162 does not teach "the first and second release profiles *are designed to coordinate* with cellular biochemical processes" (emphasis added to the functional language). Santini et al. '162 clearly disclose the reservoir caps as biodegradable (column 6, lines 13-47; column 9, lines 5-7).

G. With regards to claim 84, the Appellant argues that the plurality of layers disclosed by Santini et al. '162 can't be laser drilled since "Santini's bald mention of a monolithic stent/microchip device is not-enabling". It is noted that dependent claim 84 is a product-by-process claim. As recited in M.P.E.P. 2113, ""[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)".

H. With regards to claims 59-61, the Applicants argue that Santini et al. '162 does not teach an expandable device comprising an expandable body formed of a plurality of struts, and a plurality of openings in the plurality of struts. Santini et al. '162 clearly disclose "*integrating one or more*

drug delivery microchips into/onto a stent, such as a vascular stent" (see column 14, lines 64-66). Figure 9A of Santini et al. '162 is an exemplary embodiment of drug delivery microchips integrated onto a stent. As an alternate embodiment, Santini et al. '162 clearly disclose "*In another embodiment, stents can be designed and fabricated to have drug reservoirs and caps as part of the stent itself, that is, not as a separate microchip device, but rather as part of a monolithic stent device*". It should be noted that this portion of the disclosure teaches "drug reservoirs and caps" as monolithically formed with the stent structure. The disclosure of Santini et al. '162 offers a few examples of stent structures that are well known in the art (see column 11, lines 5-12), which examples includes expandable stent structures comprising a plurality of struts and drug(s)/agent(s) deposited therein (e.g., US 5,670,161; US 5,464,450). The Examiner maintains that the disclosure of Santini et al. '162 is enabling, and will enable one of ordinary skill in the art to reduce to practice the above-mentioned teaching: "*stents can be designed and fabricated to have drug reservoirs and caps as part of the stent itself, that is, not as a separate microchip device, but rather as part of a monolithic stent device.*"

I. With regards to claim 62, the Applicants argue that Santini et al. '162 does not teach "the same active agent in different concentrations". Santini et al. '162 teach that the first and second active agents can be the same or different (see column 4, lines 38-41). Further, Santini et al. '162 teach the subject matter of using the same drug in different amounts and/or concentrations (column 2, lines 10-12).

J. With regards to claim 85, the Appellant argues that the plurality of layers disclosed by Santini et al. '162 can't be laser drilled since "Santini's bald mention of a monolithic stent/microchip device is not-enabling". It is noted that dependent claim 85 is a product-by-process claim. As

recited in M.P.E.P. 2113, ""[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)".

K. With regards to the combination of independent claim 74 and dependent claims 82 and 83, the Appellant argues that Santini et al. '162 "is completely silent about the release profiles of the molecules from their respective reservoirs, and certainly fails to describe release profiles". It should be noted that the language of claim 49 requires blocking or retarding "delivery of the first and second active agents to the luminal side of the device body through the openings". As clearly shown in the exemplary embodiment of Figure 9c, the reservoir cap is facing the luminal side of the device, and said reservoir cap will "block or retard delivery of the first and second active agents to the luminal side of the device body through the openings". In the embodiment shown in Figure 2D, since there is a barrier layer (reservoir cap 530b) between first active agent layer 540a and second active agent layer 540b, then the release profiles will inherently be different. The release profile is either by passive release, or by active release.

L. With regards to claim 75, the claim recites the following intended purpose: "wherein the first and second active agents are arranged to be delivered to a mural side of the device body". With regards to the direction (e.g., mural or luminal) of drug delivery, Santini et al. clearly teaches the drug delivery reservoirs as disposed into or onto the stent (see column 14, lines 63-66), and the skilled artisan will be left with the choice of deciding the direction of drug delivery, depending

on the intended purpose. If the drug delivery reservoirs are disposed into the stent, then the drugs will be exposed (after degradation of the barrier layer) to either the mural or luminal side of the stent.

M. With regards to claim 76, the Appellant argues: "nowhere does Santini disclose to the skilled artisan that a stent has one reservoir including an anti-proliferative and another reservoir including an anti-inflammatory or the direction that these should be delivered from the stent". It is noted that claim 76 broadly claims "wherein the first active agent is an anti-proliferative and the second active agent is an anti-inflammatory", but it is silent as to one reservoir including an anti-proliferative and another reservoir including an anti-inflammatory. Santini et al. '162 teach that the first and second active agents can be the same or different (see column 4, lines 38-41). Examples of the drug/agent (e.g., anti-inflammatory) to be delivered are disclosed in column 9, lines 34-67. The use of stents carrying anti-proliferative and/or anti-inflammatory agents/drugs is well known in the art (column 2, lines 28-32).

N. With regards to claim 77, the Appellant argues that Santini et al. '162 does not teach "a barrier layer adjacent a luminal side of the device body which blocks or retards delivery of the first and second active agents to the luminal side of the device body through the openings". As clearly shown in the exemplary embodiment of Figure 9c, the reservoir cap is facing the luminal side of the device, and said reservoir cap will "block or retard delivery of the first and second active agents to the luminal side of the device body through the openings". In the embodiment shown in Figure 2D, since there is a barrier layer (reservoir cap 530b) between first active agent layer 540a and second active agent layer 540b, then the release profiles will inherently be different. The release profile is either by passive release, or by active release.

O. With regards to claim 78, the Appellant argues that Santini et al. '162 does not teach "the barrier layer is formed within the openings". Figure 2D clearly shows reservoir cap 530b (i.e., a barrier layer) formed within the openings. Also, reservoir cap 530a (i.e., a barrier layer) may include a portion that is disposed within the openings (column 2, lines 6-8).

P. With regards to claim 81, the Appellant argues that Santini et al. '162 does not teach "the first and second release profiles *are designed to coordinate* with cellular biochemical processes" (emphasis added to the functional language). Santini et al. '162 clearly disclose the reservoir caps as biodegradable (column 6, lines 13-47; column 9, lines 5-7).

Q. With regards to claim 86, the Appellant argues that the plurality of layers disclosed by Santini et al. '162 can't be laser drilled since "Santini's bald mention of a monolithic stent/microchip device is not-enabling". It is noted that dependent claim 86 is a product-by-process claim. As recited in M.P.E.P. 2113, ""[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)".

For the above reason, it is believed that the rejection should be sustained.

Respectfully submitted,

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March 23, 2006

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